Citation:

López-Fontana CM, Sánchez-Villegas A, Martínez-Gonzalez MA, Martinez JA. Daily physical activity and macronutrient distribution of low-calorie diets jointly affect body fat reduction in obese women. *Appl Physiol Nutr Metab.* 2009 Aug; 34(4): 595-602.

PubMed ID: 19767793

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To investigate the interaction between habitual physical activity and the carbohydrate (CHO)-fat distribution in two hypocaloric diets and the impact of such interplay on body composition changes.

Inclusion Criteria:

- Females
- Aged 20 to 50 years
- Body mass index (BMI) 29.5kg/m^2 or more
- Self-reported regular menses
- Healthy, as determined by a trained physician.

Exclusion Criteria:

- High blood pressure
- Diabetes mellitus
- Drug-treated hyperlipidemia
- Participation in a clinical trial during the last three months
- Following unconventional dietary habits, such as vegans.

Description of Study Protocol:

Design

Randomized controlled trial lasting 10 weeks.

Dietary Intake/Dietary Assessment Methodology

- Subjects were supervised weekly by the same dietitian to adjust their compliance with the

diet
- All volunteers kept records of daily food intake throughout the 10-week study.

Intervention

- Subjects were randomly assigned to consume one or two experimental hypocaloric regimens with difference macronutrient content for 10 weeks
  - *Low-carbohydrate, high-fat diet:* 40% to 45% CHO, 15% to 20% protein and 35% to 40% fat
  - *High-carbohydrate, low-fat diet:* 55% to 60% CHO, 15% to 20%protein and 25% to 30% fat
- The energy content of the diets was individually prescribed for each subject to include a 600-calorie daily deficit
- Each volunteer received a plan detailing the food distribution, quantities of each food, weekly meal menu, quantity of oil permitted per day, recipes and cooking techniques and specific suggestions.

Statistical Analysis

- Differences in anthropometrical, metabolic and physical activity-related variables according to the type of diet were compared using student's T-tests if the quantitative variable followed a normal distribution
- If the distribution of quantitative variables was not normal, a non-parametric test (Mann-Whitney U test) was used
- The association between changes in anthropometrical and metabolic characteristics of the participants throughout the experimental time and the reported and measured physical activity estimates were analyzed using parametric tests (Pearson coefficient)
- Means and coefficients were adjusted for age to avoid potential confounding
- The interaction between the type of diet consumed and physical activity was assessed through a two-way factorial analysis of variance (ANOVA)
- $P<0.05$ was considered to be statistically significant.

Data Collection Summary:

Timing of Measurements

- Subjects underwent anthropometric and substrate oxidation measurements on day one and day 70 (10 weeks)
- A physical activity questionnaire was administered at the beginning of the study
- All subjects kept daily food records throughout the 10-week study.

Dependent Variables

- Anthropometric measures included measured height, weight, waist and hip circumference, arm circumference and skinfold thickness
- Body composition was measures by bioelectrical impedance analysis
- Substrate oxidation was determined using indirect calorimetry.

Independent Variables

- Dietary intake data was collected using daily food records
- Physical activity was determined using a validated questionnaire.

Control Variables

Age.

Description of Actual Data Sample:

- *Initial N:* N=40 women
- *Attrition (final N):* N=40 women with 19 subjects in the low-CHO, high-fat group and 21 subjects in the high-CHO, low-fat group
- *Mean age:* Low-CHO group 34.2±6.2 years; High-CHO group 34.5±7.9 years
- *Anthropometrics:*
  - Average BMI and body fat percentage in the enrolled sample were 37.1±6.1kg/m^2 and 43.3%±5.3%
  - No statistical differences were found between the diet groups with regards to anthropometrics, RMR, macronutrient oxidation or physical activity estimations
- *Location:* Spain.

Summary of Results:

- Anthropometric changes were similar in both dietary groups. Both groups lost a similar amount of weight and fat mass, and reduced BMI similarly.

	Low-carbohydrate, High-fat	High-carbohydrate, Low-fat
Weight (kg)	-7.82±2.84	-7.34±2.68
BMI (kg/m^2)	-3.03±1.07	-2.90±1.07
Fat mass (kg)	-6.23±2.66	-6.07±2.74

- Subjects who were less active and had a higher CHO intake showed a greater decrease in fat mass ($P<0.05$). Obese women who were more physically active lost less fat mass when assigned to the high-CHO, low-fat diet group ($P<0.050$).

Author Conclusion:

Physical activity and the macronutrient content of energy-restricted diets, when designed to promote body fat mass reduction, should be considered together to better predict the outcome.

Reviewer Comments:

None.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	No
2.4.	Were the subjects/patients a representative sample of the relevant population?	???
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A

3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes

6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	No
6.6.	Were extra or unplanned treatments described?	No
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	???
7.6.	Were other factors accounted for (measured) that could affect outcomes?	No
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	No
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes

9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes